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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is an express request to file a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

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TENTATIVE INVENTOR(S)

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NO | Additional Inventors are being name on the separately numbered sheets attached.

TITLE OF THE INVENTION (500 characters max)

Plastic Brachytherapy Sources

Correspondence Address

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PATENT TRADEMARK OFFICE

ENCLOSED APPLICATION PAPERS (check all that apply)

X	Specification	Number of pages	16		CD(s), Number	
X	Drawings	Number of sheets	5		Other (specify)	Acknowledgment postcard Certificate of Express Mailing
X	Application Data Sheet. See 37 CFR 1.76 – 2 sheet(s)					

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

X	Applicant claims small entity status. See 37 CFR 1.27. A check or money order is enclosed to cover the filing fee.	
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government

X No.

Yes, the name of the U.S. Government Agency and the Government contract number are :

Respectfully submitted:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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Re: New U.S. Provisional Patent Application
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is being deposited in the United States Postal service as Express Mail in an envelope bearing sufficient postage, addressed to MAIL STOP PROVISIONAL PATENT APPLICATION, P.O. Box 1450, Alexandria, VA 22313-1450 on **August 20, 2003.**

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PLASTIC BRACHYTHERAPY SOURCES

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FIELD OF THE INVENTION

This invention relates to medical devices and their manufacture and use, in particular sources of radiation for treating tumors, namely brachytherapy sources.

BACKGROUND OF THE INVENTION

Advancements in the arts of plastic materials and fabrication methods make possible implementation of advanced designs of brachytherapy sources, particularly those sources that emit short-range radiation such as beta particles or low energy x-rays. These types of sources are used for treatment of various types of cancer such as tumors of the prostate, head and neck, lung, liver, breast and others. Typically they are implanted in the tumor, or in the tumor-invaded volume of tissue. There are two types of implants, permanent and temporary. As the categories imply, the temporary implants are associated with equipment for removal of the sources after a few hours or days of radiation treatment. Conversely, permanent implants are placed in the body and remain there for the life of the patient. This is possible because the permanently implanted sources have a relatively short half-life, so that the radiation is completely dissipated after a few months, during which time it has destroyed the cancer. And further, the materials of construction of the sources are biocompatible.

The most commonly used sources of radiation for permanent implants, today are radioactive iodine-125 or radioactive palladium-103 encapsulated in very small metallic tubular containers, e.g. of typical approximate dimensions: 4.5 mm in length and 0.8 mm

in diameter. However, the principles and methods taught herein apply as improvements to those and to other sources and source designs, such as custom-molded intracavity irradiators using any of a variety of radiation therapy sources such as Pd^{103}, I^{125}, Ir^{192}, Co^{60}, Yb^{196}, Sr^{89} and P^{32}. Only the short-lived isotopes are used as permanent implants.

These radioactive sources, commonly called seeds, are designed around material constraints which include requirements that a) the capsule must be sufficiently transparent to the curative radiation so that it does not unduly diminish or distort the radiation field around the seed, b) yet it must be visible to fluoroscopic or x-ray film examination, so that the physician can determine seed placement, c) it must be strong enough to prevent damage which might permit leakage of the radioactive source material out of the capsule, and d) all surfaces which are in contact with body tissue and fluids must be biocompatible. In addition, it is desirable for the seed to have a shape or other property that permits connecting seeds and spacers so that the implanted seeds are somewhat constrained from migration from the intended implant location.

Currently available seeds meet the above-identified constraints with varying success by balancing conflicting requirements such as strength vs. transparency of the capsule to the emitted curative radiation, or fluoroscopic visibility vs. uniform radiation field. In the following teaching it is shown how the use of new materials to make seeds allows innovative new balances between the several conflicting requirements, with designs that have significant economic and medical advantages over currently available products.

ILLUSTRATIVE SUMMARY OF THE INVENTION

The new materials being referred to are generally polymers, either organic or inorganic, and are commonly referred to as plastics. These durable materials are usually composed of the light elements that are transparent to low energy x-rays, many are bio-compatible, radioactive material can be dispersed in them, and they can be precisely and economically formed by current fabrication methods such as milling, injection molding, extrusion and casting.

In this Illustrative Summary, theradioactive source materials chosen as examples are palladium-103 or iodine-125. Consideration of the differences between these two source materials will illustrate the dependence of plastic seed design on properties such as x-ray energy, isotope concentration, chemical element metabolization by the body, and source of supply of the isotope. These same principles can then be applied in accordance with the invention to other therapeutically useful isotopes.

The titanium metal capsule that is conventionally used to encapsulate the radioactive material to make an implantable source (or seed) serves two purposes. It creates a sealed source for purposes of transport and handling, and it also protects the patient from the often-soluble radioactive material in the implanted seed. The major disadvantages of the metal encapsulation are cost and degradation of performance because of distortion of the radiation field around the seed. The use of a plastic capsule in accordance with the present invention mitigates against both of these disadvantages. High-strength plastic capsules create a satisfactory sealed source. They are essentially transparent to the emitted therapeutic radiations and therefore do not significantly distort the radiation field around the seed. And significantly, they have an economic advantage because less radioactive material is required to produce a seed, and the manufacturing methods available for producing seeds are fundamentally less expensive than for forming and sealing a metal capsule.

The new concept of using a plastic capsule for a seed has the additional advantage of the possibility of economically forming a special coupler on each end of the seed. The coupler can be used for a variety of functions such as connecting seeds and spacers together to make a strand of seeds. The coupler also provides a mechanism for attaching a retaining element that can prevent the strand of seeds from leaving the implantation needle until the therapist has positioned the strand satisfactorily. The coupler can also be used to connect the seeds into planar arrays for implantation into surgical wounds to irradiate cancer cells beyond the surgical margin. The coupler can also be used to connect to small dispensers of medicines for treatment of the region in and near the implant. The

coupler can also be used to provide special enhancements for imaging such as enhanced visibility on ultrasound, MRI, fluoroscopy, diagnostic x-ray or during concomitant external beam radiation therapy.

Many of the advantages of a plastic capsule can be realized by simply replacing the metal capsule of conventional seeds. While the wall thickness of the plastic will be greater, and the internal components of the conventional seed design would need to be modified to fit in the smaller available space, the resulting seed performance would be greatly improved.

Additional advantages can be achieved by using a plastic matrix to contain the radioactive components inside the capsule. For example, radioactive iodine contained in an appropriate plastic matrix is released only very slowly in the event of accidental damage to the capsule.

One aspect of the present invention is the therapeutic system comprising 1.) a seed comprised of a plastic capsule, 2.) containing a therapeutic radioactive source, and 3.) a means of visualizing the seed with diagnostic x-ray. 4.) Additionally, couplers on each end of the seed enable connections to auxiliary devices including 5.) spacers, fixers, imaging enhancers, and dispensers of medicines.

Another aspect of the invention is means of fabricating such seeds.

A further aspect of the invention is a means of deploying such seeds.

DESCRIPTION OF THE DRAWINGS

Figure 1. A plastic seed in which the radioactive source material is substantially uniformly mixed in the solid cylindrical core (1). The core is covered with a thin protective layer (2) of non-radioactive plastic.

Figure 2. A plastic seed in which the radioactive source material is substantially uniformly mixed in the solid cylindrical core (1). The core is contained in a sealed hollow plastic cylinder.

Figure 3. A plastic seed in which the radioactive source material (1) is located in the ends of a cylindrical cavity in a sealed hollow plastic cylinder (2). The cylindrical cavity also contains a marker (3), such as a metal cylinder, that is readily visible to fluoroscopy or x-ray imaging.

Figure 4. A plastic seed as in Figure 3 with the addition of a ball joint (4) on each end of the plastic cylinder.

Figure 5. A plastic seed as in Figure 2 with the addition of a ball joint (4) on each end of the plastic cylinder.

Figure 6. A plastic seed as in Figure 5 with a ball joint (4) on each end of the plastic cylinder. A "fixer" (15) is attached to one end of the seed. A spacing element (spacer), or other special attachment, is attached to the other end of the seed.

Figure 7. Examples of four types of connecting members (connectors) which can connect seeds in the types of arrays illustrated in Figure 8.

Figure 8. Examples of four different arrays of seeds that can be assembled with the connectors of Figure 7.

Figure 9. The end of a connector ball joint illustrating an example of a slot in the ball to facilitate assembly and disassembly of the joint.

Figure 10. Example of a flexible joint with substantially the same properties of a ball joint in the seed connector application. This is a type of rotating shaft coupler that is commonly called a "universal joint" in the field of mechanical engineering.

Figure 11. A plastic seed as in Figure 3 with the addition of a cylindrical socket (5) on each end of the plastic cylinder. Also shown are spacers (6) with cylindrical protrusions (10) on each end, which fit into the cylindrical sockets (5). The protrusions (10) are held in place in the sockets either by friction fit or by bonding such as by sonic welding or laser welding.

Palladium

Palladium-103 may be produced by either of two different processes: 1) Irradiating palladium-102 in a nuclear reactor, which produces palladium-103 by capture of a neutron i.e., Pd^{102} $(n,\gamma)Pd^{103}$, and 2) Irradiating rhodium-103 with a charged particle from a cyclotron or other accelerator to produce, for example, palladium-103 by the reaction $Rh^{103}(p,n)Pd^{103}$ in which a proton is captured while a neutron is simultaneously ejected from the rhodium nucleus.

The difference between the two products is that in the case of the cyclotron process, the palladium produced can be chemically separated from the rhodium target to yield carrier-free Pd^{103}. Carrier-free Pd^{103} has a specific activity of 74,700 Curies per gram. By contrast, the reactor process produces Pd^{103} in a palladium target, thus the Pd^{103} produced cannot be chemically separated from the other Pd isotopes present. This results in Pd^{103} with a much lower specific activity, a result with significant implications for therapeutic seed design.

Of the six stable isotopes in naturally occurring palladium, Pd^{102} amounts to only 1%. In the highest flux nuclear reactors currently operating worldwide, it is only marginally possible to make a useful Pd^{103} seed from neutron capture in a natural palladium target. This limitation can be overcome either by using palladium enriched in the 102 isotope, or by mixing the less expensive reactor-produced Pd^{103} with some carrier-free cyclotron-produced Pd^{103}.

Of the several palladium seeds commercially available at this time, all are encapsulated in a titanium metal shell. The amount of source radiation that is emitted from the seed is reduced by 30% to 60% from shielding by the capsule and other internal materials used in the different seed designs. As will be shown in the following, it is possible to design a plastic seed that absorbs less than 2% of the source radiation if the source material is either carrier-free or is not too diluted with non-radioactive carrier.

The seed design shown in Figures 3, 4 and 5 show the radioactive material in cavities at each end of the seed. The radioactive palladium, iodine or other isotope can be incorporated in a plastic such as an epoxy and then inserted into the seed's plastic capsule. The mixture can first be solidified into a pellet shape and then inserted, or the mixture can be solidified in place in the capsule. However, any method of fixing the radioactive material in place, such as supporting it on or in a graphite, light metal or ceramic pellet, will still retain many of the advantages of an all-plastic seed, and thus are also within the concept of the present invention.

In order to use the potentially more plentiful reactor-produced material in a conventional metal-encapsulated seed, it is necessary to use palladium targets which are highly enriched in the 102 isotope to many times the naturally occurring 1% (see Russell U.S. Patent 4,702,228, claim 1), i.e., by a factor or 20 to 70 corresponding to enrichments of 20% to 70% in Pd^{102}. In contrast, it is possible to produce economical plastic seeds from reactor-produced Pd^{103} using targets of palladium enriched to only a few times the naturally occurring 1%, i.e., by a factor of 2 to 6 corresponding to the much more economical enrichments of 2% to 6%.

If the total amount of palladium in the seed is high enough, it will absorb some of the source radiation. However, it will also be visible on an x-ray film or fluoroscope screen, eliminating the need for a separate x-ray marker in the seed (see Figs. 1, 2, 5 and 6). As will be shown later, there is a balance between these two effects which depends upon

seed design parameters as well as amount of the diluting non-radioactive palladium present.

Palladium metal has been reported to be biocompatible. The metal powder has been injected into patients with no reported adverse consequences. This means that with the use of plastic materials as revealed in this application, it is possible to consider the design of a permanently implantable seed that dissolves over a time long enough for the radiation to decay away, completing its therapeutic function, and then leaving the treatment volume with no material residue from the therapeutic implant. A biodegradable seed may be desirable for treating certain types of cancer such as breast cancer and some head and neck cancers.

Iodine

The other radioactive isotope in wide use for permanent implants is I^{125}. Because of its longer half life, it has a maximum specific activity of 17,600 Curies per gram. To aid in its radiochemical purification, non-radioactive carrier iodine is sometimes added, thus lowering the specific activity.

The ready commercial availability of I^{125} from a number of nuclear reactor facilities around the world makes it less expensive than Pd^{103} that is typically produced in cyclotrons. (Radioactive palladium can also be produced in a nuclear reactor, but it requires use of palladium enriched in Pd^{102}.) Also, its longer half-life of 57.43 days (vs. 16.99 days for palladium) makes the commercial distribution of the product less time-sensitive and thus more reliable. With appropriate adjustments of concentration and isotopic composition, I^{125} can be used in any of the seed geometries described herein for Pd^{103} seeds.

Free iodine in body fluids has a strong tendency to accumulate in the thyroid. In the rare occasion of a damaged seed being implanted in a patient, as much as half of the iodine

released by the seed may accumulate in the thyroid gland. Some iodine seeds contain iodine that is chemically or physically constrained in the seed so that in the event of an implanted seed being damaged, the iodine is released slowly over time. This means that much of the iodine will have decayed before it has a chance to escape from the seed and into the body fluids. One approach to confining the iodine is to chemically confine it within a plastic matrix and make a pellet from the plastic composite to be placed in the seed capsule.

A preferred way of making an iodine seed is to bond the iodine with a particulate, for example silver-doped activated carbon or zeolite, that slows its release, and then to make a pellet by mixing the powder into a plastic matrix that further slows any release of free iodine. The pellet is further enclosed in a capsule or coating.

General-Purpose Rotatable Connector

Because it is medically desirable, in some procedures, to attach several seeds together to make a "string of seeds," several means for accomplishing this end have been disclosed in the last few years. For example, these include Langton, et al, U.S. Patent 5,460,592, Coniglione U.S. Patents 5,713,828; 6,163,947 and 6,347,443, Horowitz U.S. Patent 4,697,575, Coniglione, et al. U.S. Patent 6,589,502, Grimm U.S. Patents 6,010,446 and 6,450,939 and Russell, et al. U.S. Patent 4,784,116.

In the present invention, it is our concept to take advantage of the relative ease with which very small objects can be formed in plastic. That opens the possibility of the kind of seed designs described hereinin which the seed ends are specifically shaped to enable exceptional coupling functions.

The present invention provides an innovative modification that is to form a general-purpose rotatable connector on the seed ends. This allows rotation, or bending, of the joint between seed and spacer, thereby avoiding the fragility of prior attempts at joining

seeds and spacers. Such a connection (7) is illustrated in Fig. 6. Embodiments of seeds adapted to employ such a connector are illustrated in Figs. 4, 5 and 6.

The joint also can serve the function of an attachment mechanism that permits adding specific functional units to a seed as illustrated in Fig.6. In that figure, one end shows a "fixer" (15) that prevents longitudinal migration of the seed. The petals of the fixer spread and stop motion of the seed. For example, a fixer (15) at each end of a string of seeds would block motion in either direction and therefore "fix" the seed position. Optionally, the petal array of a single fixer can be arranged to prevent seed motion in either direction.

Another functional unit is a plug (not separately illustrated) that can optionally be attached to the end of the seed train oriented toward the sharp leading end of the needle, the malleable plug forming a seal if required or a simple retaining element depending on interference with the interior wall on the needle so that the seed train will only leave the needle as a result of the force applied by the therapist during the implant procedure. The plug can be made with a plastic foam such that it is readily imaged with ultrasound so that the physician can easily detect the first seed leaving the needle. The plug could negate the need for the stylet to keep the connected string of seeds from falling out of the needle.

Another optional functional unit is a small capsule (not separately illustrated) that dispenses, locally, medication such as anti-inflammatory drugs, a local anesthetic, or antibiotics at a controlled rate.

Another such functional unit (not separately illustrated) is a spacer or attachment that is composed of a material that couples to a radio frequency electromagnetic field, to allow treatment of an organ with both radiation and hyperthermia.

Another such functional unit (not separately illustrated) is a spacer or attachment that contains a material which improves visibility with medical equipment such as MRI, x-ray, or ultrasound.

Another functional unit is a half-spacer (not separately illustrated) that separates and positions the seeds by a fixed amount in the needles used for the implant procedures.

Other functional units are 2-way, 3-way, 4-way and 6-way connecters as shown in Fig. 7. These connecters can be used to connect seeds in the flexible arrays diagrammed in Fig. 8. The different mesh types produced can be linear, hexagonal, square or triangular, depending upon the requirements of the physician.

The spherical cavities (sockets 4) molded into the ends of the seeds shown in Figs. 4, 5 and 6 and the spherical ends (balls 8) of the various functional units are designed and sized so that they snap together both for ease of assembly and disassembly and so that they are positively joined. The socket (4) may have slits formed into its spherical walls so that the ball end of the attachments may flex the socket wall to ease entry of the ball. Alternatively, the construction materials of the ball and/or the socket may be chosen to be pliable enough to allow assembly without need for the slits, and yet be stiff enough to adequately hold the parts together. Or, the ball (8) can be formed with slits (9) to allow it to yield on insertion and snap into place, see Figure 9.

One recurring problem with medical implantation of seeds in tissue is that, occasionally, the seeds jam in the needle and cannot be implanted without removing the needle from the patient. This involves extracting the seeds from the needle, reloading a new needle and attempting to implant a second time. However, the connectors described herein can be manufactured in several diameters. They can have a diameter larger than that of the seeds. This allows the suture to be sized so that it cannot bend or fold inside the needle and cause a jam. However, enlarging the connector diameter reduces the space between the connector and the tube wall. This reduces the flow area around the suture so that rapid withdrawal of the needle from tissue can sometimes alter the position of the

implanted seeds. The flow area can be restored by fluting the connectors, i.e., by making longitudinal grooves on the surface of the connector body.

Another type of connector can be fabricated as part of the seed. This differs from the rotatable coupler (7) described in the preceding paragraphs only in that the balls are formed on the ends of the seed and the spherical cavity is in the attachments.

Seeds and spacers may also be formed with a ball on one end and a spherical cavity on the other. This facilitates assembling strings of seeds either with spacers separating the seeds, or alternatively connecting seeds without spacers as requested by some physicians.

Or alternatively, the ability to economically fabricate complex shapes in plastic allows those skilled in the art to form a variety of types of connectors that are functionally similar to the preferred ball and spherical cavity joint described. For example Figure 10 shows a miniature type of mechanical universal joint that behaves much like a ball joint. However, the small size of permanent implants, such as the currently used palladium and iodine seeds, places limits on the complexity of practical connector designs for these seeds.

Some of the advantages of the rotatable coupler are: 1) Seeds and spacers can easily be disassembled and reassembled by the user to meet changing circumstances. 2) The resulting structures firmly snap together, but retain robustness and flexibility due to the ball-joint design. 3) A variety of auxiliary therapeutic features may be attached to the seeds, using the ball-joint feature.

A simple connector that retains most of the advantages of the ball joint is shown in Figure 11. In this configuration, instead of the spherical cavity (4) of the ball joint, a cylindrical cavity (5) is used in which a cylindrical plug or protrusion (10) on spacers (6) or attachments may be inserted. The plugs (10) can be held in place by friction, or more robustly, by bonding by using, for example, sonic welding or laser welding.

Examples of Plastic Seed designs

The following are examples of plastic seed designs based on the preceding principles. They illustrate specific embodiments of the invention.

The first configuration to be discussed in detail herein (Figure 4) illustrates most of the advantages to be gained from encapsulating the radioactive material in a plastic capsule. The seed is a standard dimension, 0.81 mm diameter and 4.5 mm long. The ends of the seed each provide for a general purpose connector (a ball joint). X-ray visibility is provided by the metal marker cylinder (3) at the seed center. The radioactive isotope (1) is contained in cavities at symmetrical positions on the seed axis near the ball joints at the ends of the seed.

Cyclotron-produced Pd^{103} has a very high specific activity. If it is diluted by a factor of 20 with non-radioactive palladium to aid in the chemical processing, the specific activity is still 74,700/20 equals 3,735 Curies per gram. Putting 3 mCi of palladium in the seed requires 0.8 micrograms of palladium that results in the palladium blocking only 0.2% of the x-rays from escaping the active region. The plastic capsule is also nearly transparent to the x-rays so that the total transmission of the x-rays in the direction perpendicular to the seed axis is about 98%. This is to be compared with about 50% transmission for most seeds currently on the market.

The high specific activity of I^{125} means that it also can be used in the configuration shown in Figure 4 and will have equally low absorption losses.

Palladium and iodine both emit low-energy electrons and soft x-rays that do not have therapeutic value because of their short range. The plastic wall of the capsule is approximately 0.2 mm thick, which is sufficient to stop these low-energy radiations.

The specific activity of reactor-produced Pd^{103} depends upon several factors. These include the intensity of the neutron flux in the reactor, the reactor operating cycle and

schedule, and the Pd^{102} enrichment of the palladium target. A flux of $2x10^{15}$ neutrons per cm^2 per second and an operating cycle of about 23 days on and 4 days down are characteristic of the HFIR test reactor at Oak Ridge National Laboratory. Two cycles of irradiation of a palladium target enriched to a few times the 1% natural abundance to 6% Pd^{103} will produce palladium with a specific activity of approximately 10 Curies/gram after allowing 17 days for the high-energy gamma emitter, metastable Pd^{109}, to decay to insignificance. If the length of the two sources (1) in Figure 4 is extended to 1 mm, nearly filling the cavity not occupied by the marker (3), the total source volume is 0.00025 cm^3. Three mCi of Pd^{103} with specific activity of 10 Curies/gram has a mass of 0.0003 grams. The density of palladium in the source region is then 0.0003/0.00025 equals 1.2 grams/cm^3. The transmission of palladium x-ray radiation out of the source capsule perpendicular to the seed axis is 0.74. The seed therefore has an apparent activity of 0.74x3 equals 2.2 mCi. These considerations indicate that it is possible to manufacture a commercial palladium seed, of this design, using palladium enriched to 6% in Pd^{103}.

Those skilled in the art, using the computational ideas illustrated in the previous paragraph can show that increasing the source volume permits using lower specific-activity palladium. The source volume can be increased in the plastic seed design by increasing the length of the source region as is illustrated in Figures 5 and 2. A further increase in source volume can be attained by increasing the source radius as shown in Figure 1. It is possible to produce a useful palladium seed using the Figure 1 design with reactor-produced palladium enriched to only 2% in Pd^{103}.

Seed designs, in which there is significant loss of the source radiation from self-absorption in the source material, also have sufficient absorption of x-rays to be visible on a fluoroscope screen or diagnostic x-ray plate. For transmissions of about 0.5 or more, the seeds are sufficiently visible for the post-implant documentation. For some designs this negates the need for a conventional heavy-metal x-ray marker in the seed.

Plastic Construction Materials

Plastic materials to be considered in design of plastic capsules and spacers in accordance with the present invention include such biocompatible plastics as PEEK-OPTIMA® manufactured by Invibio, VECTRA liquid crystal polymer manufactured by Ticona LLC, ultra-high-density polyethylene and polypropylene. The high melting temperature of PEEK (343 degrees centigrade) makes this a preferred choice especially if high temperatures are expected to be encountered, e.g. in sterilization. However, there are many other plastic materials which those skilled in materials science will find to be appropriate and satisfactory for a variety of different applications.

Composition of Radioactive Source Material for a Pd^{103} Seed of the Current Invention

The following example is intended to illustrate the formulation of a source material that is essentially free of internal x-ray absorption and is thus produced from carrier free Pd^{103} from a proton accelerator. Many persons skilled in the art are familiar with methods for extracting Pd^{103} from rhodium cyclotron targets and its subsequent purification. An example includes Carden, U.S. Patent 5,405,309. At the end of the purification process, the solution containing the Pd^{103} is concentrated into a very small mass of material, for instance 25 Ci of Pd^{103} contained in a final mass of approximately 200 mg. This concentration step is necessary for two reasons: 1) because the volume available within the seed for the source material to occupy is very small (approximately 0.8 μL), the Pd^{103} activity per unit of source material must be correspondingly large (approximately 20 Ci per ml) and 2) the radioactive concentrate acts as a diluent in the solidified polymer, and if this effect is too large, the curing properties and mechanical strength of the cured polymer may be adversely modified.

A desirable property of the source material is that it solidifies into a hard and durable "pellet" once it has been delivered to the desired location within the seed. To satisfy this requirement, we have developed an epoxy formulation with thermally initiated polymerization.

Finally, delivery of the source material into the desired location within the seed is problematic. When considered in relative terms, the problem can be summarized as the necessity to deliver a very precise volume of fluid to the bottom of a long narrow cavity. A solution to this problem is to use a single-jet, drop-on-demand, fluid-jet print head to deliver a precise number of drops into the cavity of the seed shell. This however adds the requirement that the source material must have a viscosity and surface tension that will facilitate jetting.

As an example of the foregoing, the following formulation was found to satisfy the above requirements (percentages are weight percent):

1. Radioactive residue 17%
2. Triethyleneglycoldivinylether 55%
3. UVR6110 (CRYACURE resin from Union Carbide) 18%
4. Borontrifluoride monoethylamine 2%
5. Propylene carbonate 8%

To perform the manufacturing method disclosed herein, the radioactive residue is dissolved in components 2 and 3, while component 4 is dissolved in a portion of the solvent 5. All of the liquids are then combined to form the source material. The source material is then jetted in the proper quantity into the volume of the seed shell that it is to occupy, and the source material is then heated to approximately 190°C, to initiate curing.

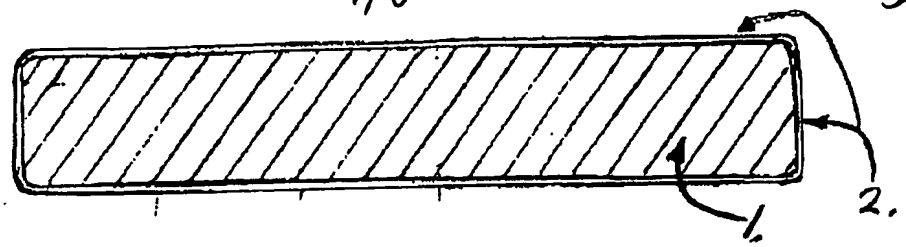


Fig. 1.

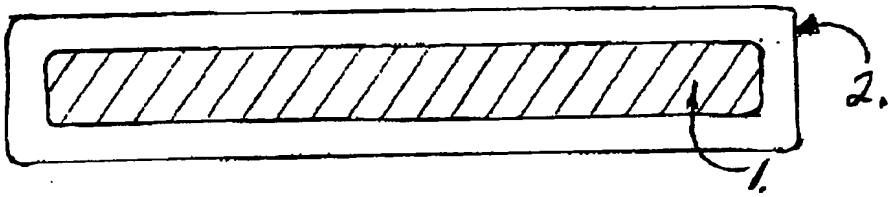


Fig. 2.

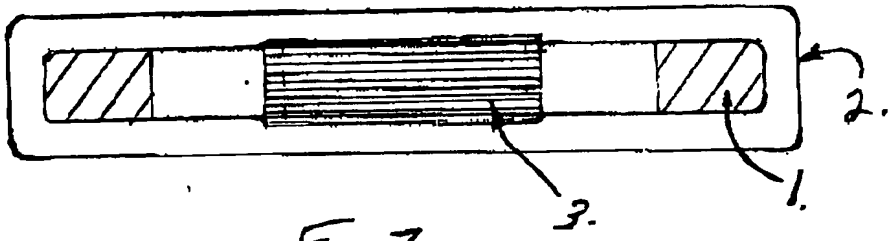


Fig. 3.

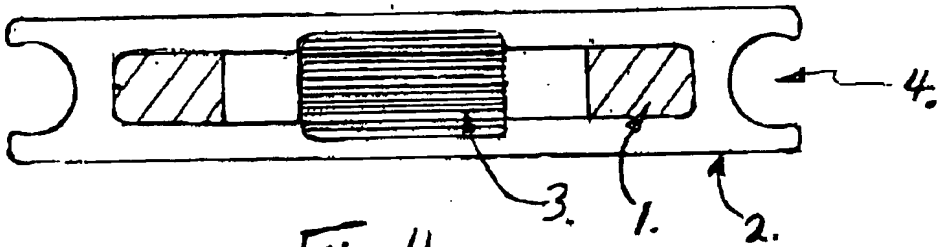
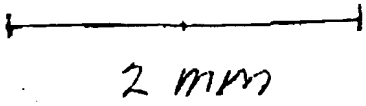
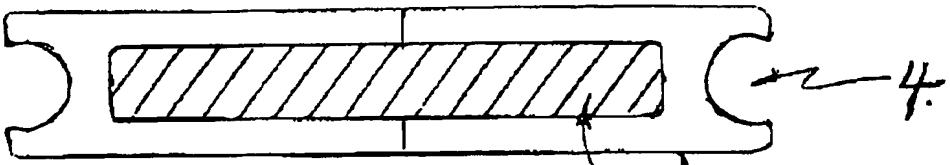


Fig. 4.





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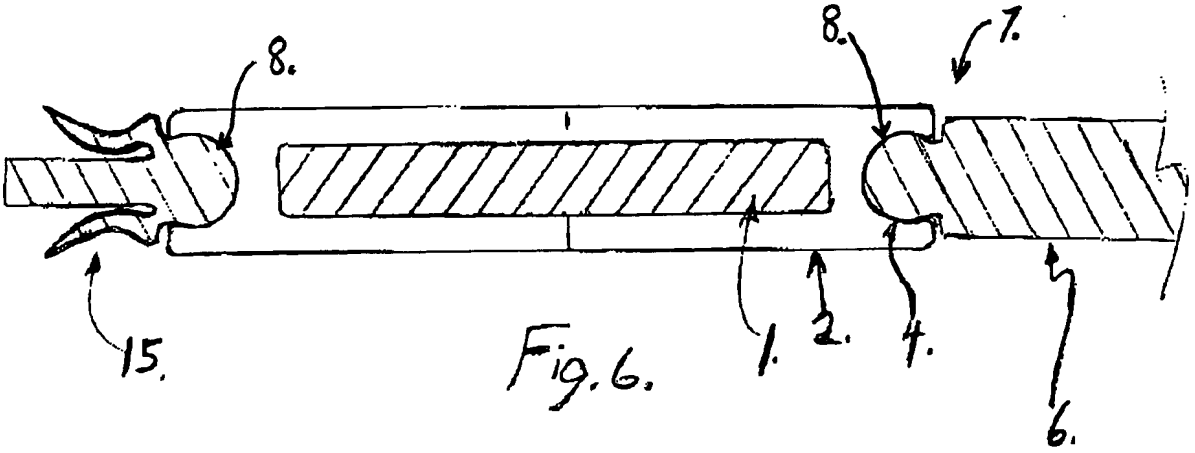

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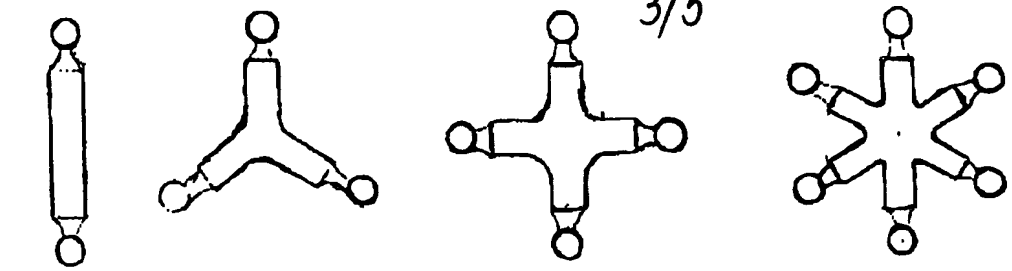

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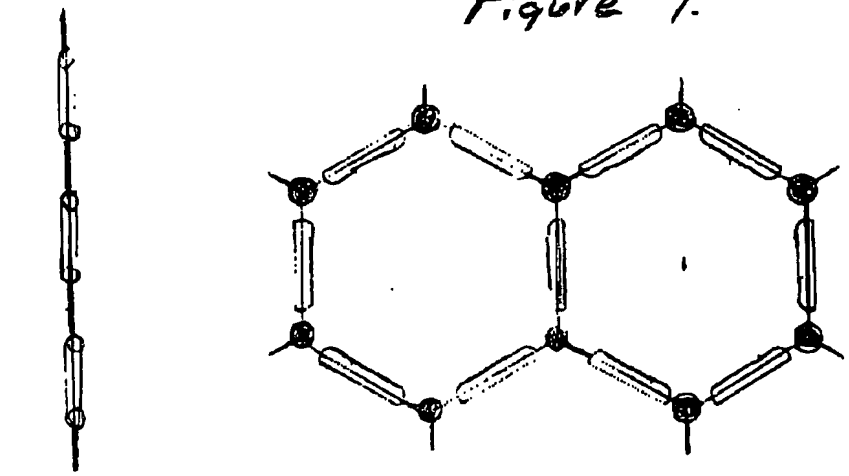

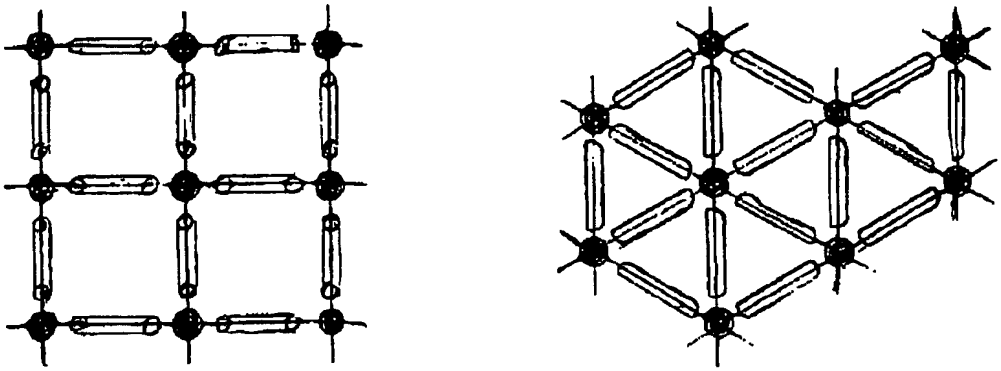

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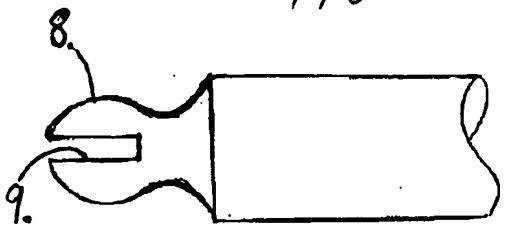

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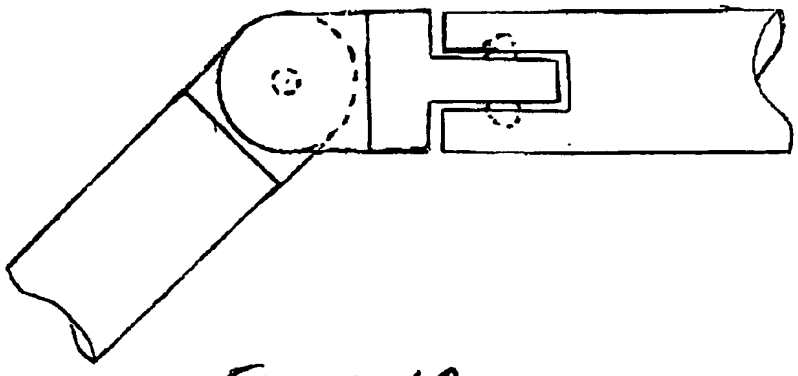

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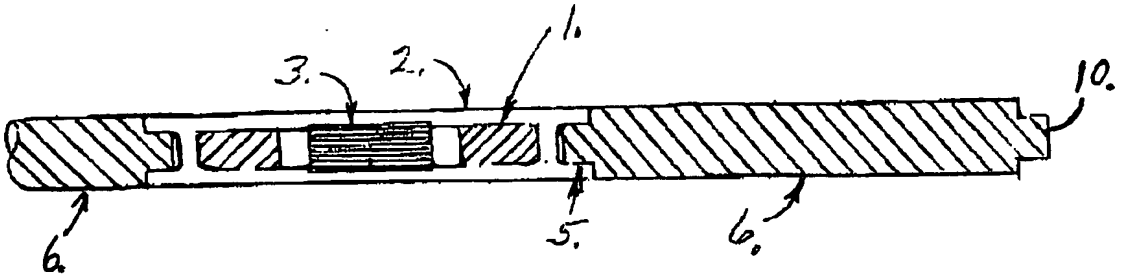

Fig. 11

Application Data Sheet

Application Information

Application Type:: Provisional

Subject Matter:: Utility

Title:: Plastic Brachytherapy sources

Attorney Docket Number:: IBT1.068

Total Drawing Sheets: 5

Small Entity:: Yes

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Representative Information

Representative Customer Number:	003775

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